

CLAIM STATUS

Claim 2 was previously cancelled. Claims 3, 13, 15, and 19 were previously withdrawn. Claims 1 and 20 are amended. Support for amendment to claims 1 and 20 may be found throughout the specification, including for example at page 11, lines 10-15, and Figures 1 and 2.

No new matter has been added.

Claims 1, 4-12, 14, and 16-18, and 20 are pending.

**REMARKS RELATING TO THE FINAL OFFICE ACTION
DATED DECEMBER 7, 2006 AND ADVISORY ACTION
DATED MARCH 12, 2007 IN THE PARENT APPLICATION**

Rejection under 35 U.S.C § 102 – Anticipation

The Examiner issued a 35 U.S.C § 102(b) rejection of claims 1, 2, 6, 9-11, 14, 17, 18 and 20 as being anticipated by U.S. Pat. No. 5,865,723 to Love (Love). Specifically, the Examiner asserted that the Love reference teaches all the elements of Applicants' claims because it is clear from the figures of Love that the distal and proximal ends of the stent coincide with the distal and proximal ends of the tissue graft, respectively.

Applicants disagree with the Examiner's rejection because the cited reference does not teach, show or even suggest all of the elements of Applicants' claims.

As amended claims 1, 2, 6, 9-11, 14, 17 and 18 are directed to stent tissue graft prostheses that include

a first expandable stent having a first distal stent end and a first proximal stent end, a tubular wall and a passage extending longitudinally therethrough,

a tissue graft having a distal tissue graft end and a proximal tissue graft end and disposed on said first stent, and

a tubular member having a wall and a passage extending longitudinally therethrough, said tubular member being disposed over said tissue graft and around said first stent and retaining said tissue graft disposed on said first stent,

wherein ***a most distal end of the first distal stent end*** is at least coincident with ***a most distal end of the distal tissue graft end*** and ***a most proximal end of the first proximal stent end*** is at least coincident with ***a most proximal end of the proximal tissue graft end*** to prevent the tissue graft from everting or folding into the passage of the first expandable stent.

As amended, independent claim 20 is directed to a stent tissue graft prosthesis that includes:

a first expandable stent having a first distal stent end and a first proximal stent end, a tubular wall and a passage extending longitudinally therethrough,

a multilayered tissue graft construct having a distal construct end and a proximal construct end, a tubular wall and a passage extending longitudinally therethrough and disposed on said first stent, and

a second expandable stent having a tubular wall and a passage extending longitudinally therethrough, said second stent being disposed over and around said construct and said first stent, and retaining said construct disposed on said first stent,

wherein **a most distal end of the first distal stent end** is at least coincident with **a most distal end of the distal construct end** and **a most proximal end of the first proximal stent end** is at least coincident with **a most proximal end of the proximal construct end** to prevent the multilayered tissue graft from everting or folding into the passage of the first expandable stent.

Specifically, the text of the specification of the Love reference does not teach stent tissue graft prostheses, where **the most distal end of the first distal stent end** is at least coincident with **a most distal end of the distal tissue graft end** (claim 1) or **of the distal construct end** (claim 20) and **a most proximal end of the first proximal stent end** is at least coincident with **a most proximal end of the proximal tissue graft end** (claim 1) or **of the proximal construct end** (claim 20) to prevent the tissue graft or the multilayered tissue graft from everting or folding into the passage of the first expandable stent.

Although, the Love reference teaches vascular prostheses that include inner and outer support elements with tissue between the inner and outer support elements, there is no teaching or suggestion whatsoever in the text of the specification of the Love reference of the most proximal and most distal ends of a first (inner) stent (inner support element) being at least coincident with the most proximal and most distal ends, respectively, of the tissue graft or the multilayered tissue graft construct.

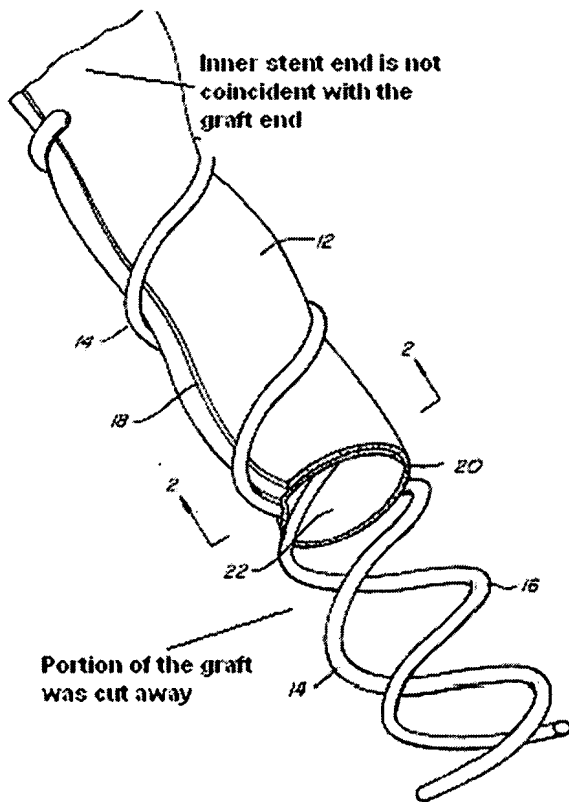


FIG. 1.

Also, none of the figures of Love illustrate stent tissue graft prostheses where *both*, the most proximal and most distal ends of the first (*inner* or inner support element) stent are coincident with the most proximal and most distal ends, respectively, of the tissue graft to prevent the tissue graft from everting or folding into the passage of the first expandable stent. For example, the top portion of figure 1 of the Love reference does not show the most proximal end of the inner stent to be coincident with the most proximal end of the graft. Furthermore, because the prosthesis of figure 1 has a portion of the tissue cut away, in absence of specific

teaching in the text of the specification of Love, one would not conclude that the most distal ends of the tissue would have been at least coincident with the most distal ends of the inner helical element 16.

Similarly, figures 2 and 3 of Love do not show that the most distal and most proximal ends of element 14 coincide with the ends of tissue 12.

Although figure 4 of the Love reference illustrates the outer sleeve 30 coinciding with the ends of tissue 12, the most proximal and most distal ends of *inner* helical element 16 are not shown to coincide with the ends of tissue 12. Because Applicants require the most distal and most proximal ends of the first (or *inner*) expandable stent (inner support element) to at least coincide with the ends of the tissue graft, Applicants' prostheses differ from the prosthesis illustrated in the figure 4 of Love.

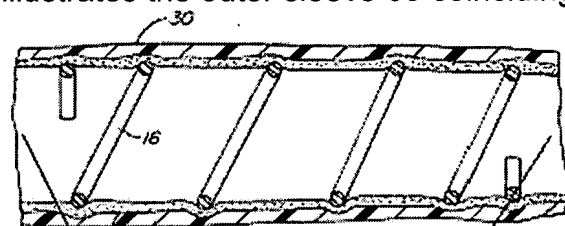


FIG. 4.

Most proximal and most distal ends of the inner stent 16 are not coincident with the ends of graft 12

Likewise, figures 5-8 of the Love reference do not show Applicants' prostheses. Rather, figures 5-8 illustrate a method of preparing the prosthesis of Love, where it is clear, especially from figures 6, 7 and 8 that both, the most proximal end and most distal end, of the *inner* helical support element 16 do not coincide with the respective ends of tissue 12. In fact, it is shown in figures 7 and 8 that the tissue extends beyond one end of the inner helical support element 16.

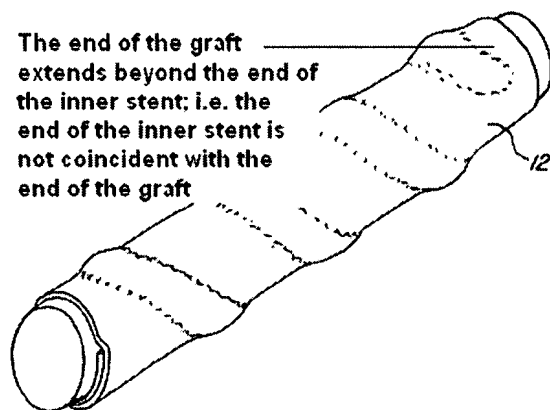


FIG. 7.

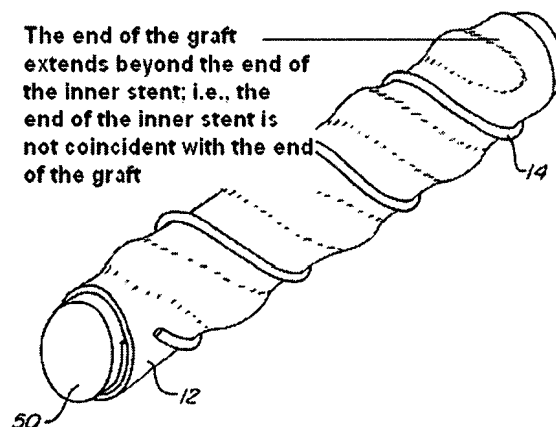
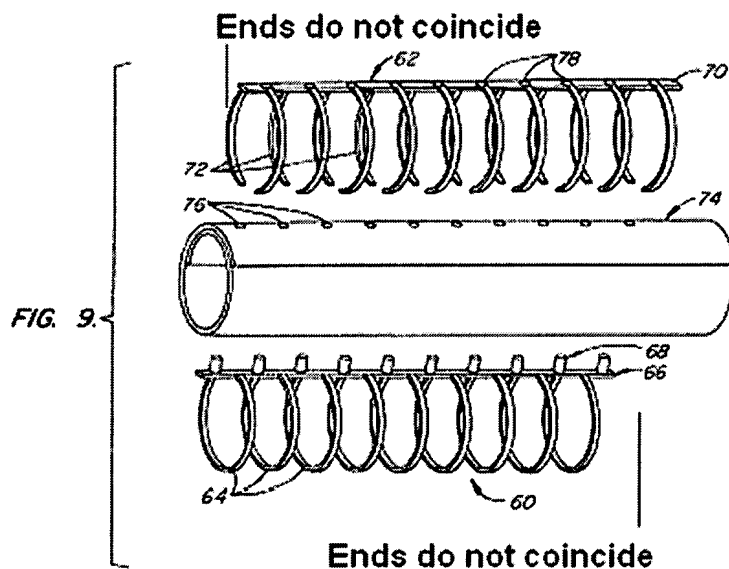


FIG. 8.

Lastly, none of the figures 9-12 illustrate the most proximal and most distal ends of the *inner* structural element coinciding with the respective ends of the tissue.



Because there is no teaching or suggestion whatsoever in the cited reference of both, most proximal end and most distal end of the first (or inner) stent coinciding with the most proximal end and most distal end, respectively, of the tissue graft or multilayered tissue graft construct, the Section 102(b) rejection of claims 1, 2, 6, 9-11, 14, 17, 18, and 20 that was predicated on Love should not be applied against amended claims 1, 2, 6, 9-11, 14, 17, 18, and 20.

Rejection under 35 U.S.C § 103 – Obviousness

The Examiner also issued a 35 U.S.C § 103(a) rejection of claims 4, 5, 7, and 8 as being unpatentable over Love in view of U.S. Pat. No. 6,358,284 B1 to Fearnot *et al* (Fearnot *et al.*); and rejection of claims 1, 12, and 16 as being unpatentable over U.S. Pat. No. 5,628,788 to Pinchuk in view of Fearnot *et al*.

Applicants disagree with the Examiner's rejections for the following reasons.

As discussed above, neither the text of the specification nor the figures of the Love reference teach, show or even suggest stent tissue graft prostheses that include a first (inner) expandable stent having a first distal stent end and a first proximal stent end, a tubular wall and a passage extending longitudinally therethrough; a tissue graft having a distal tissue graft end and a proximal tissue graft end and disposed on said first stent; and a tubular member having a wall and a passage extending longitudinally therethrough, said tubular member being disposed over said tissue graft and around said first stent and retaining said tissue graft disposed on said first stent, wherein ***the most distal end of the first distal stent end*** is at least coincident with ***the most distal end of the distal tissue graft end*** and ***the most proximal end of the first proximal stent end*** is at least coincident with ***the most proximal end of the proximal tissue graft end*** to prevent the tissue graft from everting or folding into the passage of the first expandable stent.

Likewise, neither the text of the specification nor the figures of the Pinchuk reference teach or show stent tissue graft prostheses that include a first (inner) stent with ***most proximal*** and ***most distal ends*** that are at least coincident with the ***most proximal*** and ***most distal ends***, respectively, of a tissue graft. Although, the Examiner asserted that figures of Pinchuk clearly show that the distal and proximal ends of the

stent coincide with the distal and proximal ends of the tissue graft, respectively, Applicants respectfully point out that none of the figures of Pinchuk actually illustrate stent tissue graft prostheses where both, the most proximal and most distal ends of the *inner* stent are coincident with the respective ends of the tissue graft to prevent the tissue graft from everting or folding into the passage of the first expandable stent. "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Specifically, figures 1-6 do not illustrate Applicants' prostheses. Rather, figures 1 and 2 of Pinchuk illustrate a basic stent; figures 2 and 3 illustrate a graft (textile tube); and figures 5 and 6 illustrate a stent graft (stent over graft).

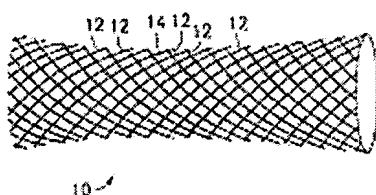


FIG. 1
PRIOR ART
Stent

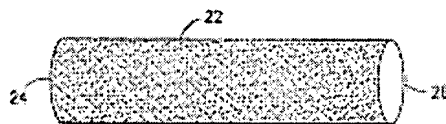


FIG. 3
Graft

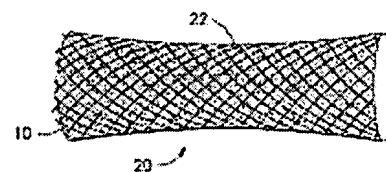


FIG. 5
Stent graft

Likewise, figures 7-12 do not show Applicants' invention. Rather, figures 7-12 of Pinchuk are cross-sectional views of various exemplary stent graft configurations and illustrate only small *portions* of the devices. Because there is no specific teaching in the text of the specification of Pinchuk that the most proximal and most distal ends of the inner stent 10 at least coincide with the most proximal and most distal ends, respectively, of the graft 22, and figures 7-12 illustrate only small *portions* of the actual devices (rather than entire device), one of skill in the art would not conclude that the figures 7-12 of the Pinchuk reference teach or suggest most proximal and most distal ends of the *inner* stent coinciding with the respective ends of the graft.

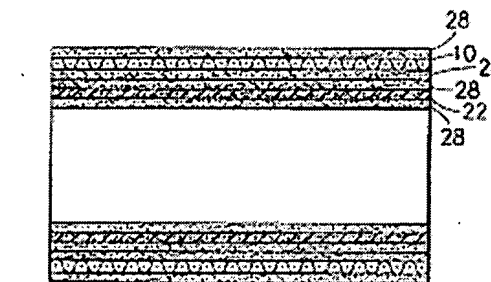
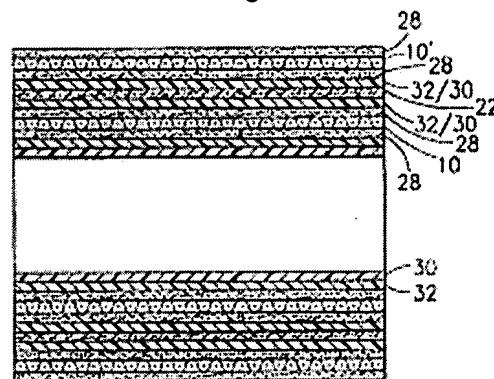


FIG. 7

FIG. 12



Furthermore, figures 13-18 of Pinchuk do not teach Applicants' prostheses because none of these figures illustrate an *inner stent* and, as such these figures can not teach the most proximal and most distal ends of the *inner stent* being at least coincident with the ends of the graft.

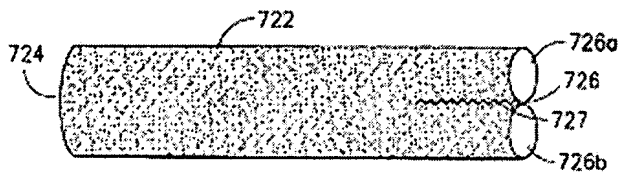


FIG. 13

No inner stent present

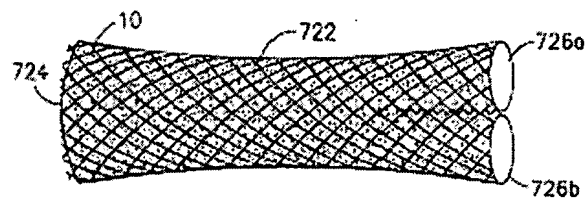


FIG. 15

No inner sent present

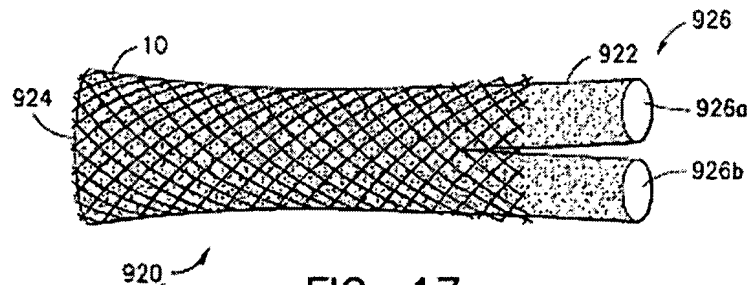


FIG. 17

No inner stent present

Although, the Pinchuk reference states that the inner stent may be included with the devices of figures 13-18, there is no teaching or suggestion whatsoever in the Pinchuk reference of the **most proximal** and **most distal ends of the inner stent** being at least coincident with the **most proximal** and **most distal ends**, respectively, **of the graft**. Clearly there is no teaching or suggestion whatsoever in the Pinchuk reference of all the elements of Applicants' claims 1, 12, and 16.

Furthermore, nothing in the Fearnot *et al.*, reference suggests modifying the prosthesis of Love or Pinchuk to include an *inner stent with ends, where the most proximal and most distal ends of the inner stent are at least coincident with the most proximal and most distal ends, respectively, of a tissue graft* to prevent the tissue graft from everting or folding into the passage of the first expandable stent.

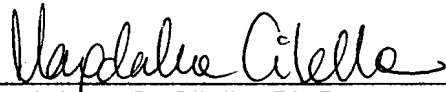
Accordingly, the stent tissue graft prosthesis of Applicants' claims 1 is both novel and non-obvious. As such, the prostheses defined by the claims depending on claim 1, are also novel and non-obvious. In particular, claims 4, 5, 7, and 8 are not obvious under 35 U.S.C. §103 over Love in view of Fearnot *et al.*, and claims 1, 12, and 16 are not obvious under 35 U.S.C. §103 over Pinchuk in view of Fearnot *et al.* Applicants request that this rejection not be applied against amended claims 1, 4, 5, 7, 8, 12, and 16.

SUMMARY

Applicants respectfully submit that present application is now in condition for early allowance. If, for any reason, the Examiner feel a discussion would expedite the prosecution of this application, the Examiner is kindly invited to contact the undersigned at (312) 245-5398.

Respectfully submitted,

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